

**REMARKS**

This amendment is expected to require further consideration and/or search. Accordingly, this amendment has been filed with a Request for Continued Examination.

This application is amended in a manner to place it in condition for allowance at the time of the next Official Action.

**Status of the Claims**

Claim 17 is amended to include some of the features of claim 1, from which it ultimately depended, i.e., to recite spraying as a means to form a matrix into which an active ingredient is incorporated and to clarify two types of composition that may be prepared.

Claim 25 has been amended to utilize a pharmaceutical composition formed in in-situ, e.g., as previously described in claims 8, 9 and 13.

New claim 33, which depends from claim 25, further defines the skin disorders to be treated, e.g., as discussed in Example 6.

New claim 34 further depends from claim 17 and includes some of the features from claim 1.

New claim 35 is a method of delivering a drug to the skin, i.e., as described in claim 25 and previously pending claims 8, 9 and 10.

Support for the amended and new claims may be found at the following locations in the originally filed specification and claims:

- (a) page 5, first 5 lines of second paragraph;
- (b) page 6, first line of first full paragraph and first 6 lines of second full paragraph;
- (c) page 7, lines 3 and 4;
- (d) page 8, line 3;
- (e) page 9, lines 6 to 9;
- (f) page 10, lines 2 to 4 of the last paragraph; and
- (g) original claim 15.
- (h) Example 6.

Claims 1-16 and 18-24 have been cancelled without prejudice.

Claims 17 and 25-35 remain in this application.

**Claim Rejections-35 USC §102 and 35 USC §103**

Claims 1-5, 8-12, 16, 22 and 25 were rejected under 35 U.S.C. §102(b) as being anticipated by US 4,450,151 ("‘151").

Claims 15, 21, 24 and 26-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over ‘151.

Claims 17 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over ‘151 in view of GORDON US 6,001,336 ("GORDON").

Claims 6 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over ‘151 in view of HALSWANTER et al. US 6,841,146 ("‘146").

These rejections are respectfully traversed for the reasons that follow.

The independent claims 17, 25 and 35 each require the formation of a coherent porous matrix with an active ingredient or drug in situ on the skin of an individual from a composition (i) or (ii). Claim 17 describes the generic formation of such a matrix, which involves spraying the composition (i) or (ii) onto the skin. Claim 34 describes administering a drug by utilizing the coherent porous matrix based on the same composition (i) or (ii), and Claim 25 describes treating skin disorders utilizing the coherent porous matrix based on the composition (i) or (ii).

The '151 document relates to power aerosol composition, which are principally used as antiperspirants, water-eczema remedies, dry shampoos or baby powders (See col. 1, lines 11 and 12) ), in which an intentional medicine may be added as an optional feature (col. 1, lines 55 to 59), and in which a powdered material is suspended in alcohol and water. A liquefied gas propellant is employed as a separate phase (see col. 2, lines 49 to 58). There is absolutely no suggestion, however, that document '151 prepares in situ a depot composition comprising particles of a solid excipient and a drug directly on the skin by spraying a composition for a predetermined time to build up such a depot, i.e., as recited in independent claims 17, 25, and 35.

Document '151 further differs from the claimed invention in average particle size. Document '151 utilizes particles of between 325 to 70 mesh, i.e., between 44 to 210  $\mu\text{m}$ . This is larger than either the excipient particle size described

in composition (i), i.e., at least 90% by weight being less than 50  $\mu\text{m}$  and at least 50% being at least 0.1  $\mu\text{m}$ , or the drug and solid excipient composite particles of composition (ii), i.e., at least 50 % are larger than 10 $\mu\text{m}$  and at least 90 % are smaller than 150 $\mu\text{m}$ . See independent claims 17, 25 and 35.

GORDON is unable to remedy these shortcomings of document '151 for reference purposes. GORDON relates simply to a method for spray drying hydrophobic drugs. In this respect, it is not a method for preparing a pharmaceutical composition, but rather is a method for drying something and therefore is not at all relevant to the claimed invention.

The '146 document also fails to remedy the shortcomings of the '151 document for reference purposes. The '146 document relates to a gel formulation in which a thixotropic agent is mixed with water and drug in order to create a gel. Clearly, this is not a particulate formulation at any stage of its preparation, and certainly not something that is used to form a matrix, as claimed, on the skin. Rather, it is a gel formulation suitable for use in the nasal cavity, and is therefore in no way relevant to the present invention. Indeed, Example 8 of the present application, demonstrates the significant advantages of the claimed invention to a conventional gel, e.g., as taught by the '146 document.

Therefore, document '151 fails to anticipate independent claims 17, 25 and 35, as well as dependent claims 26-34, and

neither '151 alone nor the combination with GORDON and/or '146 renders obvious these claims.

Withdrawal of the rejection is respectfully requested.

**Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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